Position of the Council at first reading

Position of the Council at first reading with a view to the adoption of a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2000/75/EC as regards vaccination against bluetongue
COUNCIL OF THE EUROPEAN UNION

Brussels, 15 December 2011
(OR. en)

16696/1/11
REV 1

Interinstitutional File:
2010/0326 (COD)

AGRILEG 124
VETER 48
CODEC 1977
PARLNAT 326

LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject: Position of the Council at first reading with a view to the adoption of a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2000/75/EC as regards vaccination against bluetongue
- Adopted by the Council on 15 December 2011
DIRECTIVE 2011/.../EU
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of

amending Directive 2000/75/EC as regards vaccination against bluetongue

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43(2) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee¹,

Acting in accordance with the ordinary legislative procedure²,

¹ OJ C 132, 3.5.2011, p. 92.
Whereas:


(2) In the past, only sporadic incursions of certain serotypes of the bluetongue virus were recorded in the Union. Those incursions mainly occurred in the southern parts of the Union. However, since the adoption of Directive 2000/75/EC, and particularly since the introduction into the Union of bluetongue virus serotypes 1 and 8 in the years 2006 and 2007, the bluetongue virus has become more widespread in the Union, with the potential to become endemic in certain areas. It has therefore become difficult to control the spread of that virus.

(3) The rules on vaccination against bluetongue laid down in Directive 2000/75/EC are based on experience of the use of so-called "modified live vaccines", or "live attenuated vaccines", which were the only vaccines available when that Directive was adopted. The use of those vaccines may also lead to an undesired local circulation of the vaccine virus in unvaccinated animals.

\(^1\) OJ L 327, 22.12.2000, p. 74.
(4) In recent years, as a result of new technology, "inactivated vaccines" against bluetongue have become available which do not pose the risk of undesired local circulation of the vaccine virus to unvaccinated animals. The extensive use of such vaccines during the vaccination campaign in the years 2008 and 2009 has led to a significant improvement in the disease situation. It is now widely accepted that vaccination with inactivated vaccines is the preferred tool for the control of bluetongue and for the prevention of clinical disease in the Union.

(5) In order to ensure better control of the spread of the bluetongue virus and to reduce the burden on the agricultural sector posed by that disease, it is appropriate to amend the current rules on vaccination laid down in Directive 2000/75/EC in order to take account of the recent technological developments in vaccine production.

(6) In order to enable the vaccination season 2012 to benefit from the new rules, this Directive should enter into force on the day following that of its publication in the *Official Journal of the European Union*.

(7) The amendments provided for in this Directive should make the rules on vaccination more flexible and also take into account the fact that inactivated vaccines that can also be successfully used outside areas subject to animal movement restrictions are now available.
(8) In addition, and provided that appropriate precautionary measures are taken, the use of live attenuated vaccines should not be excluded, as their use might still be necessary under certain circumstances, such as following the introduction of a new bluetongue virus serotype against which inactivated vaccines may not be available.

(9) Directive 2000/75/EC should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:
Article 1

Directive 2000/75/EC is hereby amended as follows:

(1) In Article 2, the following point is added:

"(j) 'live attenuated vaccines': vaccines which are produced by adapting bluetongue virus field isolates through serial passages in tissue culture or in embryonated hens' eggs."

(2) Article 5 is replaced by the following:

"Article 5

1. The competent authority of a Member State may decide to allow the use of vaccines against bluetongue provided that:

   (a) such decision is based on the result of a specific risk assessment carried out by the competent authority;
   
   (b) the Commission is informed before such vaccination is carried out.

2. Whenever live attenuated vaccines are used, Member States shall ensure that the competent authority demarcates:

   (a) a protection zone, consisting of at least the vaccination area;
(b) a surveillance zone, consisting of a part of the Union territory with a depth of at least 50 kilometres extending beyond the limits of the protection zone.

(3) In Article 6(1), point (d) is replaced by the following:

"(d) implement the measures adopted in accordance with the procedure laid down in Article 20(2), in particular with regard to the introduction of any vaccination programme or other alternative measures;".

(4) In Article 8(2), point (b) is replaced by the following:

"(b) The surveillance zone shall consist of a part of the Union territory with a depth of at least 50 kilometres extending beyond the limits of the protection zone and in which no vaccination against bluetongue with live attenuated vaccines has been carried out during the previous 12 months.".

(5) In Article 10, point 2 is replaced by the following:

"2. any vaccination against bluetongue using live attenuated vaccines is prohibited in the surveillance zone.".
Article 2

1. Member States shall adopt and publish, by ...* at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall communicate immediately to the Commission the text of those provisions.

They shall apply those provisions from ...** at the latest.

When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

* OJ: Please insert the date: six months after the entry into force of this Directive.
** OJ: Please insert the date: six months and one day after the entry into force of this Directive.
Article 3

This Directive shall enter into force on the day following that of its publication in the Official Journal of the European Union.

Article 4

This Directive is addressed to the Member States.

Done at,

For the European Parliament
The President

For the Council
The President
COUNCIL OF THE EUROPEAN UNION

Brussels, 16 December 2011

Interinstitutional File:
2010/0326 (COD)

16696/1/11
REV 1 ADD 1

STATEMENT OF THE COUNCIL'S REASONS

- Statement of the Council's reasons

Adopted by the Council on 15 December 2011
I. INTRODUCTION

On 15 November 2010, the Commission submitted to the Council a proposal for a Council Directive, based on Article 15 of Council Directive 92/119/EEC. Upon advice of the Council Legal Service, the derived legal basis of the Commission proposal was replaced by Article 43(2) of TFEU, which involves the ordinary legislative procedure.

The European Parliament delivered its opinion on 7 April 2011.

The Economic and Social Committee adopted its opinion on 15 March 2011.

In accordance with Article 294 of the Treaty, the Council adopted its position in first reading on 15 December 2011.

II. OBJECTIVES

The draft Directive aims to update the current rules on vaccination against bluetongue set out in Directive 2000/75/EC by making them more flexible. Bluetongue is a disease affecting ruminants (such as cattle, sheep and goats) and is transmitted by insect vectors that spread the virus from one animal to another. Vaccination is the preferred tool for bluetongue control and prevention of clinical disease in the EU. The use of vaccines is, however, limited by the current rules set out in Directive 2000/75/EC, that foresee the use of vaccines only in areas where the disease occurred and which have therefore been subject to animal movement restrictions. Those rules are based on experiences with the so-called "modified live vaccines", or "live attenuated vaccines" that were the only vaccines available when the Directive was adopted a decade ago. Those vaccines may lead to undesired circulation of the vaccine virus in unvaccinated animals in the areas where the vaccine has been used. The new flexible rules introduced by the draft Directive are based on the fact that inactivated vaccines are now available, which can also be successfully used outside areas subject to animal movement restrictions.

---

2 Doc. 5498/11.
3 P7_TA-PROV(2011)0147.
4 NAT/512 - CESE 538/11.
III. ANALYSIS OF THE COUNCIL'S POSITION

The Council's position confirms the objectives proposed by the Commission and incorporates the quasi-totality of the European Parliament's first-reading amendments.

In particular, the Council shares the European Parliament's view that Article 43(2) of TFEU is the correct legal basis for this Directive. This line was confirmed by Coreper (Part I), which, following the advice of the Council Legal Service against the use of a derived legal basis for this proposal, decided at its meeting on 26 January 2011 to propose to the European Parliament such modification of the legal basis by the co-legislators, as the Commission services were unable to commit to rapid re-submission of the proposal with this modified legal basis.\(^1\)

The Council's position introduces changes to the European Parliament's first-reading opinion only in two areas:

1. While all other proposed requirements related to the communication of national provisions to the Commission are maintained in the Council's position, the specific obligation to use correlation tables is deleted. The Council considers this to be in line with the conclusion reached in horizontal negotiations between the Institutions on the issue of correlation tables and takes note of the Commission representative's confirmation that his Institution would not deem such specific requirement justified for the present Directive.

2. The other change concerns the deadline for the national transposition of the Directive.

---

\(^1\) Docs 5498/11 and 5499/11.
COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT

pursuant to Article 294(6) of the Treaty on the Functioning of the European Union

concerning the

COMMUNICATION FROM THE COMMISSION
TO THE EUROPEAN PARLIAMENT

pursuant to Article 294(6) of the Treaty on the Functioning of the European Union

concerning the


1. BACKGROUND


Date of the opinion of the European Economic and Social Committee: 15 March 2011

Date of the position of the European Parliament, first reading: 7 April 2011

Date of adoption of the position of the Council: 15 December 2011


During the discussions in the Council, no Member State objected to the text of the proposal when it was presented for technical discussions at the meeting of the Chief Veterinary Officers and at the Agricultural Counsellors attachés on 13 January 2011. The COREPER acknowledged the urgency of this matter unanimously and adopted without discussion the position of the Member States on 26 January 2011. The chair of the COREPER transmitted the Commission proposal to the European Parliament by letter on 26 January 2011, accompanied by a proposal for the modification of its legal basis to Article 43(2) of TFEU by the co-legislators following the ordinary legislative procedure. COREPER further invited the Parliament to treat this issue urgently in order to meet the deadlines of the Commission proposal.

---


The European Parliament adopted its opinion in first reading on 7 April 2011. The Commission did not modify its proposal in light of this first reading. The Council has already indicated the support to the measures proposed by the Commission and it is also ready to support the minor amendments adopted by the European Parliament.

The horizontal question of correlation tables is now the subject of an inter-institutional agreement, endorsed in the Competitiveness Council on 29 September 2011 and by the Conference of the Presidents of the European Parliament on 20 October 2011.

The Council has adopted its position at first reading on 15 December for a possible early second reading.

The opinion of the Economic and Social Committee was adopted on 15 March 2011 (NAT/512). The rapporteur is Mr Ludvik Jiřívec.

2. OBJECTIVE OF THE PROPOSAL FROM THE COMMISSION

The aim of the Commission proposal is to offer more flexibility to vaccination against the bluetongue disease, in order to allow animals to be vaccinated also outside those areas subject to animal movement restrictions.

The Commission proposal thus amends Council Directive 2000/75/EC. Article 5 is amended so that competent authorities allow vaccination against bluetongue subject to a specific risk assessment. The amendment of Article 8(2) (b) of Directive 2000/75/EC will provide that within the surveillance zone no vaccination is carried out with "modified live attenuated" vaccines. Further, the proposal provides for the amendment of Article10 (2) of the Directive to the effect that the prohibition currently imposed against any vaccination within the surveillance zone, be limited to vaccination with "modified live attenuated" vaccines; and thus it allows vaccination with "inactivated vaccines", which are safer.

In addition the Commission proposal foresees that when Member States adopt the above provisions, they shall communicate to the Commission the text of those provisions and a correlation table between those provisions and the Directive.

3. COMMENTS ON THE POSITION OF THE COUNCIL

The Council position is that Article 43(2) of TFEU should be used as legal base instead of the one proposed by the Commission because the Lisbon treaty introduced the ordinary legislative procedure for proposals based on Article 43. The Commission does not object to this change of legal base.

As the Council agrees to the possibility to vaccinate against bluetongue also outside those areas subject to animal movement restrictions, in line with the Commission proposal, the Commission supports the Council position.

Given the delays in the adoption of the proposal due to the inter-institutional debate on the issue of correlation tables, the Council intends to postpone the proposed dates of adoption and publication of the national laws, regulations and administrative provisions necessary to comply with this Directive and of application of those provisions. The Commission accepts this postponement which stays compatible with the next vaccination season.
With regard to the request for a correlation table for the present proposal, the Council is opposed to it. In light of the limited number of amendments proposed to an existing Directive transposed in national law since a decade, and the resulting easy check on their transposition, the Commission can accept that no provision on correlation tables is inserted in this Directive.

The European Parliament proposed amendments to the proposal, essentially modifying the legal base to Article 43(2), and introducing new implementation dates to ensure enforcement in time for the vaccination season. None of those amendments were controversial. However the inter-institutional discussions on the question of correlation tables blocked any progress on the proposal.

4. CONCLUSION

The Commission welcomes the Council position at first reading, which paves the way for an early second reading agreement.